

Premarket Approval (PMA) Package for
Dockets Management Branch

PMA Number P030049
Docket # 2005M-0270

Bayer HealthCare, Diagnostics Division
ADVIA Centaur® HBsAg ReadyPack Reagents,
ADVIA Centaur® HBsAg Confirmatory ReadyPack
Reagents, and ADVIA Centaur® HBsAg Quality
Control Material

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling